University of Nevada, Reno Institutional Review Board
Reporting of Unanticipated Problems Involving Risk to Subjects or Others (UPIROs) Including Adverse Events (AEs) to the IRB

Is the event unexpected (in terms of nature, specificity, severity, or frequency) given a) the research procedures described in the protocol AND b) the characteristics of the subject population being studied?

Y

Is the event related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.)

N

Is the event serious? Serious means any adverse event that results in any of the following: death, a life-threatening experience, inpatient hospitalization or prolongation of hospitalization, a persistent or significant disability/incapacity, a congenital anomaly/birth defect, or any other adverse event that, based upon appropriate medical or surgical intervention to prevent one of the other outcomes listed in this definition.

N

Does the event suggest that the research participation may place subjects or others at greater risk of harm (including physical, psychological, economic, or social harm)?

OR

Y

Will the event result in a temporary or permanent interruption of study activities by the PI or sponsor to avoid potential harm?

N

Report to the IRB immediately (if possible), but no more than 5 calendar days after the PI becomes aware of the event.

N

Report to the IRB within 5 calendar days of the PI becoming aware of the event or within 48 hours, if fatal.

N

Are either of the following true? University of Nevada PI has concluded that an immediate change to the protocol is necessary to address the risks raised by the event; OR b) the sponsor, external IRB at the site where the problem or event occurred, or DSMB has required amendments to research protocol or consent documents as a result of the event.

Y

Report to the IRB within 5 calendar days of the PI becoming aware of the event or within 48 hours, if fatal.

Y

Report to the IRB within 5 calendar days of the PI becoming aware of the event or within 48 hours, if fatal.

N

Not reportable to the IRB

*Adapted from the Yale UPIROs/AE Flowchart.*